

APR 28 2006

**510(k) Summary****Special 510 (k) Summary of Safety and Effectiveness****Company and Contact Information**

Safety Syringes, Inc.  
1939 Palomar Oaks Way, Suite A  
Carlsbad, CA 92011

Voice 760.918.9908  
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Thomas L. Hall  
Sr. Director, Regulatory Affairs & Quality Assurance

**Device Identification****Trade Names:**

1. Tamper Evident UltraSafe® Passive™ Delivery System
2. UltraSafe® Passive™ Delivery System (X-Series)

Regulation Number – 21 CFR 880.5860

Regulation Name – Syringe, Piston (accessory)

Classification – Class II

Product Code – MEG

**Predicate Devices**

1. Tamper Evident UltraSafe® Passive™ Delivery System
2. UltraSafe® Passive™ Delivery System (X-Series)  
(Subsequent to the submission of the premarket notification for this device, the trade name was changed from UltraSafe® Passive™ X-Series Needle Guard)

**Description of Modified Devices**

The Safety Syringes UltraSafe Delivery System/Needle Guard devices are anti-needlestick accessories for pre-filled ISO Standard glass syringes. ISO Standard glass syringes are supplied in multiple sizes. These devices are designed to fit syringe sizes 0.5 mL, 1.0 mL, 1.0 mL long, 1.5 mL, 2.25 mL, 3.00 mL, and 5.0 mL.

The only change from the currently legally marketed devices, and the subject of this premarket notification is the expansion of the Indications for Use, that is currently limited to healthcare professionals, to include physician prescribed medication self-injecting patients and individuals who assist self-injecting patients. There are no changes to the design of these devices, materials used to produce these devices, or to their fundamental technology.

**Indications for Use**

Single use devices that are indicated for use as an accessory with prefilled ISO Standard glass syringes to aid in the protection of healthcare professionals, patients who self-inject doctor prescribed medications, and individuals that assist self-injecting patients, from accidental needlesticks.

The intended patient population is unrestricted and may include children and adults, and parenteral methods of administration.

**Compliance with Design Controls**

Design Control activities for this device have been performed in conformance with the design control procedure requirements as specified in 21 CFR part 820.30.

**Risk Management**

Risks associated with each product family have been identified, evaluated and, after mitigation, the risks fall into the "Broadly Acceptable Region" following ISO 14971.

**Conclusion**

The expansion of the indications for use to include patients who self-inject doctor prescribed medications and individuals who assist self-injecting patients provides needed protection to an expanding population of users who can benefit with the use of anti-needlestick devices. The ability of non-healthcare personnel to understand and follow the Instructions for Use has been tested and the results of that testing indicates that the devices will perform as intended in the hands of typical non-healthcare users.

This labeling change brings the safety benefits to a new user group. No issues have arisen to indicate that this labeling change poses unreasonable risks to non-healthcare professional users.



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

APR 28 2006

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Thomas L. Hall  
Senior Director, Regulatory Affairs and Quality Assurance  
Safety Syringes, Incorporated  
1939 Palomar Oaks Way, Suite A  
Carlsbad, California 92011

Re: K060743  
Trade/Device Name: Tamper Evident UltraSafe® Passive™ Delivery System  
UltraSafe® Passive™ Delivery System (X-Series)  
Regulation Number: 880.5860  
Regulation Name: Piston Syringe  
Regulatory Class: II  
Product Code: MEG  
Dated: April 12, 2006  
Received: April 14, 2006

Dear Mr. Hall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital.

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number:

K060743

Device Name:

UltraSafe® Passive™ Delivery System

Indications for Use:

Single use devices that are indicated for use as an accessory with pre-filled ISO Standard glass syringes to aid in the protection of healthcare professionals, patients who self-inject doctor prescribed medications, and individuals that assist self-injecting patients, from accidental needlesticks.

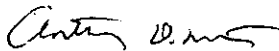
The intended patient population is unrestricted and may include children and adults, and parenteral methods of administration.

Prescription Use   X   AND/OR Over-The-Counter Use             
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



Director  
Office of Anesthesiology, General Hospital,  
Dental Control, Dental Devices

Device K060743

## Indications for Use

510(k) Number:

K060743

Device Name:

Tamper Evident UltraSafe® Passive™ Delivery System

Indications for Use:

Single use devices that are indicated for use as an accessory with pre-filled ISO Standard glass syringes to aid in the protection of healthcare professionals, patients who self-inject doctor prescribed medications, and individuals that assist self-injecting patients, from accidental needlesticks.

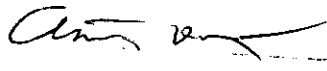
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(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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Director, General Hospital,  
Control of Dental Devices  
Number K060743